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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/01/2005

Eva Kontsekova

SONN:066US

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32425 7590 12/17/2009
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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

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12/17/2009

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10521049	11/1/2005	KONTSEKOVA ET AL.	SONN:066US

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EXAMINER

MARIA LEAVITT

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20091207

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Commissioner for Patents

Receipt of reply brief dated October 21, 2009, in compliance with Rule 41.41 is acknowledged, and the reply brief is entered.

Applicant's additional arguments submitted on 09-21-2009 in reply to the Examiner's answer filed on 07-20-2009 have been fully considered but deemed unpersuasive. Applicants essentially raise four issues: first, that the specification provides an enabling disclosure of how to make and use a transgenic animal, second, that a person of skill in the art would be able to make and use a variety of promoters with the current claims, third, claims 19 and 37 are separately patentable and, four, claim 34 is separately patentable. Insofar as the first issue, Applicants essentially contend that: 1) a correlation between the phenotype and the tauopathy has been established, 2) the transgenic animals of the invention not only exhibit neurofibrillar pathology but also other pathological features associated with Alzheimer's disease including cognitive impairment, oxidative stress, hypertension, and diabetes. See First Filipcik Declaration, para. 11; Cente et al. (Eur J Neurosci., 24(4): 1085-90 (2006), 3) a reproducible phenotype can be achieved from different animal strains and different insertional animals, 4) when the transgene was transferred from the genetic background of hypertensive SHR strain into the normotensive Wistar strain, an almost identical phenotype was exhibited, 5) transgenic rat lines #318, #72 and #24 also demonstrate that a reproducible phenotype can be achieved from different insertional events, 6) the claims are enabled for any non-human transgenic animals and the evidence demonstrates that such animals exhibit characteristics that make them suitable models for Alzheimer's disease, and 7) the cited references support the enablement for the current claims.

In relation to the second issue, sufficient guidance to make and use a variety of promoters with the current claims, Applicants essentially argue that: 8) that a number of promoters were known at the time the invention was made, 9) One of ordinary skill in the art would have had a number of known, suitable promoters at his disposal at the time the invention was filed and, 10) cloning and manipulation of previously identified DNA sequences is within the ordinary level of skill in molecular biology.

Regarding 1)- 7), Applicants have not submitted new arguments to rebut rejection of claims under 35 U.S.C. 112, first paragraph, scope of enablement, made in the Office Action filed on 08-27-2007. The examiner has already rebutted similar arguments alleged by Applicants at pages 13-21 of the Examiner's Answer filed on 07-20-2009 in response to the appeal brief filed March 13, 2009 and supplemental appeal brief filed on May 04, 2009. Therefore claims 17-37 remain rejected under 35 U.S.C. 112, first paragraph, scope of enablement, first paragraph, for the reasons of record.

Regarding 8)-10), Applicants have not submitted new arguments to rebut rejection of claims under 35 U.S.C. 112, first paragraph, scope of enablement, made in the Office Action filed on 08-27-2007. The examiner refers Applicants to the reasons of record as set forth at pages 21-23 of the office action filed on 07-20-2009.

Please note regarding the third and fourth issues submitted by Applicants, essentially addressing Applicants' contention providing support for the enablement of claims 19 and 37 as separately patentable, and claim 34, as separately patentable, that no specific new

arguments have been provided to the rejection of record. The examiner refers Applicants to the reasons already of record as discussed by the examiner at pages 23 and 24, respectively, of the office action filed on 07-20-2009.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Maria G. Leavitt
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